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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/470,944	12/22/99	GUNDLING G	6653.US.01

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EXAMINER	
SPIEGLER,A	
ART UNIT	**PAPER NUMBER**
1656	6

DATE MAILED: 09/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/470,944	GUNDLING, GERARD	
	Examiner	Art Unit	
	Alexander H. Spiegler	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *29 March 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-10 are indefinite because the claims do not recite a positive process step which clearly relates back to the preamble. The preamble states that the method is for separating nucleic acid from a test sample but the final process step is eluting the nucleic acid from the metal oxide support material. Therefore, the claims are unclear as to whether the method is a method of separating nucleic acid from a test sample or a method of eluting the nucleic acid from the metal oxide support material. This rejection may be overcome by amendment of the claims to recite "c) eluting the nucleic acid from the metal oxide support material, thereby separating the nucleic acid from a test sample".

B) Claims 1-10 are indefinite over the recitation of "contacting a test sample with a metal oxide support material with a binding buffer" because it is not clear as to what is intended to be the relationship between the support and the buffer. For example, it is not clear as to whether the sample is contacted with a support and with a binding buffer or if the sample is contacted with a support in a binding buffer.

C) Claims 9 and 10 are indefinite over the recitation of "distinct sources" because it is unclear exactly what "distinct sources" since the claim does not set forth what the sources are distinct from, e.g. distinct from some other unspecified source.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 5-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Uematsu et al. (EP 0757106 A2, 1997).

Uematsu et al. disclose a method for isolating a nucleic acid by mixing a metal oxide support, a material containing a nucleic acid, and a solution for extracting the nucleic acid forming a sample solution, separating the metal oxide support to which the nucleic acid has been bonded from the sample solution, and eluting the nucleic acid from the magnetic carrier to which the nucleic acid has been bonded (pg. 3, ln. 42-45). Uematsu et al. further teach that the solution used in the extraction of the nucleic acid contains a buffer containing a chaotropic material, such as guanidine salts, potassium iodide, sodium thiocyanate, sodium isothiocyanate, and urea (pg. 5, ln. 54-56). Furthermore, the reference teaches that the buffer can be used in combination with Triton X-100, a known detergent, and Tris HCl buffer (pg. 5, ln.56 - pg.6 ln. 1). With respect to claim 5, the reference further teaches a wash step of an aqueous solution of about 70% ethanol, following the separation of the metal oxide support/nucleic acid complex from the sample solution (pg.5, 43-44). With respect to claim 6, Uematsu et al. teach that following the wash

step the nucleic acid is then eluted form the metal oxide support, with a Tris-EDTA bufer (TE buffer), or sterilized water (pg. 5, ln. 45). With respect to claim 7, the reference further teaches the detection of the nucleic acid after eluting the nucleic acid from the metal oxide support (pg. 3, ln. 57 - pg. 4, ln. 6). With respect to claim 8, the reference further teaches the step of amplifying the eluted nucleic acid (pg. 4, ln. 8-9). With respect to claim 9 and 10, the reference teaches that the nucleic acid used is RNA or DNA, and is taken from a biological source (i.e. whole blood, urine) (pg. 2-3). With respect to claim 11, Uematsu et al. teach a kit for isolating nucleic acid comprising a metal oxide support and a solution for extracting the nucleic acid, which is composed of a chaotropic agent, a detergent, and an elution buffer comprising water (pg. 4, ln. 10-12).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uematsu et al. (EP 0757106 A2, 1997) in view of Koller (US 5128247).

Uematsu et al. disclose a method for isolating a nucleic acid by mixing a metal oxide support, a material containing a nucleic acid, and a solution for extracting the nucleic acid forming a sample solution, separating the metal oxide support to which the nucleic acid has been bonded from the sample solution, and eluting the nucleic acid from the magnetic carrier to which the nucleic acid has been bonded (pg. 3, ln. 42-45). Uematsu et al. further teach that the solution

used in the extraction of the nucleic acid contains a buffer containing a chaotropic material, such as guanidine salts, potassium iodide, sodium thiocyanate, sodium isothiocyanate, and urea (pg. 5). Furthermore, the reference teaches that the buffer can be used in combination with Triton X-100, a known detergent, and Tris HCl buffer (pg. 5, ln.56 - pg.6 ln. 16). Uematsu et al. does not teach the addition of a reducing agent in the buffer used in the extraction of the nucleic acid. However, Koller teaches of a "nucleic acid releasing composition containing a chaotropic component", which refers to chemical compositions which effectively promote the release of nucleic acids through the disruption and lysis of cells (Col. 3-4). Furthermore, Koller teaches that the nucleic acid releasing component will contain a chaotropic agent, salt, detergent, and a reducing agent (Col. 3-4). Koller (col. 4, ln. 55) teaches that the reducing agent aids in the disruption and lysis of the cells, as well as the disassociation of the proteins from the nucleic acids. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Uematsu by adding a reducing agent to the binding buffer in order to have achieved the benefit stated by Koller of enhancing the extraction and separation of the nucleic acids

7. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uematsu et al. (EP 0757106 A2, 1997) in view of Chomczynski (US 5945515).

The teachings of Uematsu et al. are presented above. In particular, Uematsu et al. teach the isolation of nucleic acids by mixing a metal oxide support, a material containing a nucleic acid, and a solution for extracting the nucleic acid consisting of a buffer containing a chaotropic agent and a detergent, separating the metal oxide support to which the nucleic acid has been bonded from the sample solution, and eluting the nucleic acid from the magnetic carrier to which

the nucleic acid has been bonded (p.3-6). Uematsu et al. does not teach a binding buffer further comprising an organic solvent and the flashpoint of the binding buffer is greater than 130 degrees Fahrenheit. Chomczynski teaches a solution for isolation of RNA, DNA, and proteins from biological material, where the solution comprises a chaotropic agent, detergent, and organic solvent (col. 10, ln. 22-34). With respect to claim 3, Chomczynski teaches that the addition of substantially lower amounts of organic solvents are required to effect the precipitation of cellular components (col. 3, ln.65-68). With respect to claims 2 and 4, Chomczynski further teaches that the solution for the isolation of RNA, DNA, and proteins, also comprises a reducing agent (see abstract, and col. 4 ln. 4). Chomczynski teaches that the reducing agent facilitates denaturation of RNase by the chaotropes and aids in the isolation of undegraded RNA. In view of the teachings of Chomczynski, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Uematsu et al. so as to have added an organic solvent to a binding buffer comprising a chaotropic agent and a detergent, or a chaotropic agent, detergent, and reducing agent, in order to have achieved the benefit of effecting the precipitation of cellular components. With respect to claims 3 and 4, the resulting binding buffer containing low concentrations of organic solvent effective to precipitate the cellular components would be expected to have a flashpoint of greater than 130^0 F. With respect to claims 2 and 4, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Uematsu by adding a reducing agent to the binding buffer in order to have achieved the advantage stated by Chomczynski of enhancing the denaturation of RNase present in the sample thereby improving the isolation of RNA from the sample.

8. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
September 7, 2000

CARLA J. MYERS
PRIMARY EXAMINER